

Substitute for form 1449B/PTO

**SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT  
IN AN APPLICATION  
LISTING OF REFERENCES**

June 11, 2008

(Use several sheets if necessary)

ATTORNEY DOCKET NO.  
3506.1021-000

APPLICATION NO.  
10/519,594

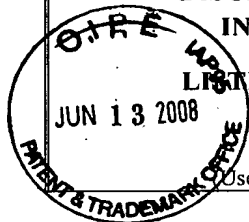
FIRST NAMED INVENTOR  
David Cavalla

FILING DATE  
December 28, 2004

EXAMINER  
Layla Soroush

CONFIRMATION NO.  
2624

GROUP  
1617



**U.S. PATENT DOCUMENTS**

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	U3	4,845,092	07-04-1989	Sanger <i>et al.</i>
	U4	4,939,136	07-03-1990	Haeck <i>et al.</i>
	U5	5,225,407	07-06-1993	Oakley <i>et al.</i>
	U6	5,352,685	10-04-1994	Maruyama <i>et al.</i>
	U7	5,434,174	07-18-1995	Gidda <i>et al.</i>
	U8	5,438,068	08-01-1995	Eeckhout <i>et al.</i>
	U9	5,470,868	11-28-1995	Young
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	U11	5,576,317	11-19-1996	Gonsalves
	U12	5,663,343	09-02-1997	van der Meij <i>et al.</i>
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	U18	5,985,866	11-16-1999	Müller <i>et al.</i>
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	U22	6,156,771	12-05-2000	Rubin <i>et al.</i>

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	U23	6,194,382	02-27-2001	Crain, <i>et al.</i>
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	U33	2002/0040033 A1	04-04-2002	Cautreels <i>et al.</i>
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	U50	2003/0158221 A1	08-21-2003	Zhang <i>et al.</i>
	U51	2003/0203055 A1	10-30-2003	Rao <i>et al.</i>
	U52	2006/0217391 A1	09-28-2006	Landau
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	U63	2005/0192270 A1	09-01-2005	Landau
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	F3	WO 88/04173	06-16-1988	Serotonin Industries of Charleston	
	F4	EP 0 297 651 B1	11-03-1993	Duphar International Research B.V	
	F5	WO 94/01095	01-20-1994	Smith-Kline Beecham PLC	
	F6	WO 96/11009	04-18-1996	Loder, Cari	
	F7	WO 98/01157	01-15-1998	The WWK Trust	
	F8	WO 98/08520	03-05-1998	Scotia Holdings PLC	
	F9	WO 98/09623	03-12-1998	Scotia Holdings PLC	
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	F13	WO 00/51583	09-08-2000	Sepracor, Inc.	
	F14	WO 00/51584	09-08-2000	Sepracor, Inc.	
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	F16	WO 02/07713 A2	01-31-2002	Solvay Pharmaceuticals GMBH	X
	F17	EP 1 230 921 A1	08-14-2002	Pfizer Products, Inc.	
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	F22	WO 03/077897 A1	09-25-2003	Cypress Bioscience, Inc.		
	F23	WO 2004/004734 A1	01-15-2004	Arachnova Therapeutics Ltd.		
	F24	WO 2004/019948 A1	03-11-2004	Arachnova Therapeutics, Ltd.		
	F25	WO 2004/058353 A3/A2	07-15-2004	Amedis Pharmaceuticals, LTD.		
	F26	WO 2004/062623 A2	07-29-2004	Dynogen Pharmaceuticals, Inc.		
	F27	WO 2004/062624 A3/A2	07-29-2004	Dynogen Pharmaceuticals, Inc.		
	F28	EP 0150469	06-15-1988	Mitsubishi Chemical Industries Limited		

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R3	"How to Avoid a Health Insurance Claim Denial- and What to do When You Can't," [Retrieved on 03-15-2005]. Retrieved from the Internet <URL:http://info.insure.com/health/claimdenial.html>, pp 1-4.	
R4	"Irritable Bowel Syndrome at a Glance - Nosology, Epidemiology, and Pathophysiology (Monograph I), December 2002 [Retrieved on 2002-12-12]. Retrieved from the Internet <URL:http://fdhn.org/html/education/gi/ibs_nosology.htm>, pp. 1-2.	
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R7	Béique, J.C., <i>et al.</i> , "Affinities of Venlafaxine and Various Reuptake Inhibitors for the Serotonin and Norepinephrine Transporters," <i>Eur. J. Pharmacol.</i> , 349(1):129-132 (1998).	
R8	Burns, M.J., "The Pharmacology and Toxicology of Reboxetine," <i>Int. J. Med. Toxicol.</i> 3(4):26 1-7 (2000).	
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R11	Camilleri, M., "Serotonergic Modulation of Visceral Sensation: Lower Gut," <i>Gut</i> 51(Supp. 1):i81-i86 (2002).	
R12	Center for Drug Evaluation and Research Application Number: 020623; Pharmacology Reviews; July 5, 1996, pp. 1-40.	
R13	Database CIN 2004-01-05, "Life Sciences in Brief," [online], January 5, 2004 (retrieved online January 31, 2006). Retrieved from: STN Database, Accession No. 33(3):1518T.	
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
R15	Depoortere, I., <i>et al.</i> , "Dose-Dependent Effects of Recombinant Human Interleukin-11 on Contractile Properties in Rabbit 2,4,6-Trinitrobenzene Sulfonic Acid Colitis," <i>J. Pharmacol. Exp. Ther.</i> , 294(3): 983-990 (2000).
R16	Drossman, D.A., <i>et al.</i> , "Irritable Bowel Syndrome: A Technical Review for Practice Guideline Development," <i>Gastroenterology</i> , 112: 2120-2137 (1997).
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R18	Fairweather, D.B., <i>et al.</i> , "The Psychomotor and Cognitive Effects of Litoxetine in Young and Middle Aged Volunteers," <i>Br. J. Clin. Pharmacol.</i> , 40(2):119-125 (1995).
R19	Gebhart, G.F., "Pathobiology of Visceral Pain: Molecular Mechanisms and Therapeutic Implications IV. Visceral Afferent Contributions to the Pathobiology of Visceral Pain," <i>Am. J. Physiol. Gastrointest. Liver Physiol.</i> 278:G834-G838 (2000).
R20	Goldberg, P.A., <i>et al.</i> , "Modification of Visceral Sensitivity and Pain in Irritable Bowel Syndrome by 5-HT <sub>3</sub> Antagonism (Ondansetron)," <i>Digestion</i> , 57(6):478-483 (1996).
R21	Greenbaum, D.S., <i>et al.</i> , "Effects of Desipramine on Irritable Bowel Syndrome Compared with Atropine and Placebo," <i>Digestive Diseases and Sciences</i> , 32(3): 257-266 (1987).
R22	Ishigooka, Jr., <i>et al.</i> , "Serotonin-Noradrenaline Reuptake Inhibitors(SNRIs)," <i>Nippon Rinsho</i> , 59, pp. 1523-9, (2001) - Abstract Only.
R23	Ito, C., <i>et al.</i> , "Effect of GK-128 [2-[(2-Methylimidazol-1-yl)methyl]- benzo[f]thiochromen-1-one Monohydrochloride Hemihydrate], a Selective 5-Hydroxytryptamine <sub>3</sub> Receptor Antagonist, on Colonic Function in Rats," <i>J. Pharmacol. Exp. Ther.</i> , 280(1): 67-72 (1997).
R24	Jin, J.G., <i>et al.</i> , "Propulsion in Guinea Pig Colon Induced by 5-Hydroxytryptamine (HT) via 5-HT <sub>4</sub> and 5-HT <sub>3</sub> Receptors," <i>J. Pharmacol. Exp. Ther.</i> , 288(1): 93-97 (1999).
R25	Kozlowski, C.M., <i>et al.</i> , "The 5-HT <sub>3</sub> Receptor Antagonist Alosetron Inhibits the Colorectal Distention Induced Depressor Response and Spinal <i>c-fos</i> Expression in the Anaesthetised Rat," <i>Gut</i> , 46: 474-480 (2000).
R26	LOTRONEX - Tablets, Product Information, GlaxoSmithKline, Research Triangle Park, NC, pp. 1-13 (2002).
R27	Mertz, H.R., "Irritable Bowel Syndrome," <i>N. Engl. J. Med.</i> 349(22):2136-2146 (2003).

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R28	Million, M., <i>et al.</i> , "Susceptibility of Lewis and Fischer Rats to Stress-induced Worsening of TNB-colitis: Protective Role of Brain CRF," <i>Amer. Phys. Soc.</i> , 276 (4 Pt 1): G1027-G1036 (1999).	
R29	Morteau, O., <i>et al.</i> , "Influence of 5-HT <sub>3</sub> Receptor Antagonists in Visceromotor and Nociceptive Responses to Rectal Distension Before and During Experimental Colitis In Rats," <i>Fundam. Clin. Pharmacol.</i> , 8(6):553-562 (1994).	
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R38	Venkova, K., <i>et al.</i> , "Peripheral Activity of a New NK <sub>1</sub> Receptor Antagonist TAK-637 in the Gastrointestinal Tract," <i>J. Pharmacol. Exp. Ther.</i> , 300(3): 1046-1052 (2002).	
R39	Wong, E.H.F., <i>et al.</i> , "Reboxetine: A Pharmacologically Potent, Selective, and Specific Norepinephrine Reuptake Inhibitor," <i>Biol. Psychiatry</i> . 47(9): 818-829 (2000).	
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